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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,663	11/29/2001	Lorraine Faxon Meisner	36091-701.501	5796

21971 7590 02/17/2010

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650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
02/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,663	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 28-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 28-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The negative limitation with respect to the exclusion of all amino acids lacks support in the Specification and claims as originally filed. The written description only discloses the use of sulphur containing amino acids. As such, there is insufficient disclosure to support the exclusion of all amino acids.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-30 are incomplete as they are dependent on cancelled claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 26, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591), The Merck Index and Yaun et al..

The claimed invention is directed to a composition containing ascorbic acid and glucosamine and water where at least a portion of the ascorbic acid is heated to the claimed range and then cooled to the claimed range and a composition consisting essentially of ascorbic acid and glucosamine and water.

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily (Column 2, lines 38-53, Column 3, Table 1, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and

supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 2, lines 40-47, Column 10, lines 6-17).

The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius (page 111).

Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively (Pages 5081, 8082).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily. The difference between Schinitsky et al. and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid and glucosamine,

water, pH of 3.5 to 4.1 and the preparation process. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucosamine (Murad), the use of ascorbic acid up to 20% (Schinitsky et al.) and that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin (Herstein). Further, The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius and Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the pH range of 3.5 to 4.1 would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid by heating the ascorbic acid to around 60 degrees Celsius in order to facilitate the solubility of higher concentrations of ascorbic acid and then cool the solution to room temperature so as to inhibit degradation of the ascorbic.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Examiner has duly considered the Applicant's declaration (12/3/2009) but deems it unpersuasive. The declarant asserts that one of ordinary skill in the art would not be able to extrapolate the teachings of the Murad declaration to topical compositions. The declarant does

not provide sufficient evidence of the same. The declarant only test a specific cream composition of which the components of the commercial cream base, other than it contains greater than 50% water, are not disclosed. The evidence only shows that there was an exothermic reaction and color change. The evidence does not show that the cream could not be applied topically or that other formulations would react the same way. Further, the declaration is not commensurate in scope with the claims as the claims are not limited to use of the commercial cream base.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The Applicant argues that Murad does not provide any guidance for the person of ordinary skill in the art to specifically select the sugar compound glucosamine, ascorbic acid among many disclosed alternatives or the remove the amino acid and transition metal compound. However, the Murad discloses the reasons for using glucoseamine and ascorbic acid as indicated above. As indicated in *KSR*, it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle. There is no need to extrapolate

from Murad as the prior art as indicated above discloses topical compositions. Further, the present claims do not exclude the amino acid or transitional metal from the claims.

The Applicant's argument that the phrase "consisting essentially of" excludes both amino acids and transitional metals does not provide evidence that the inclusion of the same would materially affect the basic and novel characteristics of the claimed invention. The Applicant's own specification indicates that non-toxic zinc salts and sulfur containing amino acids are suitable for use in the claimed invention, i.e. would have the same basic and novel characteristics of topically treating skin (Specification, paragraphs 0033 and 0060). See *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). The Applicant also presents no evidence as to how the phrase “consisting essentially of” exludes tyrosine.

The Applicant’s conclusion that one of ordinary skill in the art would not be able to prepare a topical composition is without merit. The Declaration provides no evidence that one of ordinary skill in the art would not be able to prepare a topical composition which contains glucosamine, ascorbic acid and water having a pH of about 3.5 to about 4.1. The stability study

only provides evidence that there is an exothermic reaction with the one or more components contained within the mixture of glucosamine, ascorbic acid and specific cream used. The stability study provides no evidence that the comparative product could not be applied topically. Even if the Applicant's argument was valid, then the Applicant's own specification would lack the necessary disclosure from which one of ordinary skill in the art would prepare said composition as the Specification fails to contain working examples of said composition and includes creams as a form of said composition. Finally, the point is moot as the claims do not require that the formulation or ascorbic acid itself be stable with respect to physical and/or chemical stability.

The Applicant argues that Murad does not disclose or suggest that has a pH of about 3.5 to about 4.1 as recited in the claims. However, since this is a rejection based on a combination of references there is no requirement that Murad disclose every element of the claimed invention by itself. For the same reason, the Applicant's arguments as to what each of the prior art individually do not teach do not overcome the rejection as the rejection is based on a combination of references.

The Applicant argues that Herstein would not guide one of ordinary skill in the art to incorporate the pH of Herstein into Murad with the organoclay ingredient. However, the Applicant has provided no evidence that the phrase "consisting essentially of" excludes the organo clay.

The Applicant's arguments as to stability do not overcome the rejection. The Applicant has not provided evidence that its compositions are stable. The Applicant and Specification does not show how the NMR charts show how the pretreatment process results in an ascorbic acid

composition which is more stable than an untreated ascorbic acid composition. The Applicant's own declaration shows that at least in the composition tested that there was a reaction between two or more of the ingredients in the tested composition where untreated ascorbic acid was used.

The Yaun et al. reference does not teach away from the claimed invention as Yaun et al. discloses that there is little degradation at 60 degrees compared to 100 degrees Celsius. As such, in view of the teachings of the other prior art, as indicated above, one of ordinary skill in the art would be use higher temperatures to facilitate mixing of higher concentrations of ascorbic acid and than cooling to inhibit degradation. Further, the claims include heating below 60 degrees Celsius as "about 60 degrees" is claimed. The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius. As such, one of ordinary skill in the art would expect that temperatures below 60 degrees Celsius and above 45 degrees Celsius would facilitate dissolving ascorbic acid while limiting degradation.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 25, 26, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043), The Merck Index and Yaun et al..

The claimed invention is directed to a composition containing ascorbic acid and glucosamine and water where at least a portion of the ascorbic acid is heated to the claimed

range and then cooled to the claimed range and a composition consisting essentially of ascorbic acid and glucosamine and water.

Schinitsky et al. is cited and Murad are cited for the same reasons as above are incorporated herein to avoid repetition.

Darr et al. discloses that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form and faciliates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). Darr et al. discloses that at even at a pH of 4.5, a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27).

The Merck Index and Yaun et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily. The difference between Schinitsky et al. and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, glucosamine, water, pH of 3.5 to 4.1 and the preparation process. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucoseamine (Murad), the use of ascorbic acid up to 20% (Schinitsky et al.) and that a pH of about 3.5 is preferred to facilitate entry of ascorbic acid into the skin (Darr et al.). Further, The Merck Index discloses that the

solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius and Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the pH range of about 3.5 would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid by heating the ascorbic acid to around 60 degrees Celsius in order to facilitate the solubility of higher concentrations of ascorbic acid and then cool the solution to room temperature so as to inhibit degradation of the ascorbic.

The Applicant's argument that the phrase "consisting essentially of" excludes both amino acids and transitional metals does not provide evidence that the inclusion of the same would materially affect the basic and novel characteristics of the claimed invention. The Applicant's own specification indicates that non-toxic zinc salts and sulfur containing amino acids are suitable for use in the claimed invention, i.e. would have the same basic and novel characteristics of topically treating skin (Specification, paragraphs 0033 and 0060). See *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant,

the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.).

The Examiner has duly considered the Applicant's arguments and declaration but deems the same unpersuasive for the reasons above and the further reasons below.

The Applicant argues that the stability studies in the Darr reference for pHs above 3.5 were performed in the dark at cold temperatures. However, the Applicant itself has not provided evidence that its compositions are stable. The Applicant and Specification does not show how the NMR charts show how the pretreatment process results in an ascorbic acid composition which is more stable than an untreated ascorbic acid composition. The Applicant's own declaration shows that at least in the composition tested that there was a reaction between two or more of the ingredients in the tested composition where untreated ascorbic acid was used.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
August 31, 2009

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616